

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Colombovac PMV

Vm 42058/4020

Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. Change in the manufacturing process of the active substance. 02 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure performed on a starting material used in the manufacture of the active substance. 16 July 2012 Changes to an existing pharmacovigilance system as described in the DDPS O2 September 2011 Renewal Change of name of manufacturer of the active		
the product. Addition of test for pH determination. Change of end of shelf-life specification for thiomersal content. Deletion of extraneous agents test on the finished product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. Change in the manufacturing process of the active substance. O2 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the active substance. Change in test procedure performed on a starting material used in the manufacture of the active substance. Changes to an existing pharmacovigilance system as described in the DDPS O2 September 2011 Addition of a site for secondary packaging and batch release PMarch 2011 Renewal Change of name of manufacturer of the active	27 March 2025	i i
Addition of test for pH determination. Change of end of shelf-life specification for thiomersal content. Deletion of extraneous agents test on the finished product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. 02 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Change in the procedure for the active substance. Change in test procedure for the active substance. Change in test procedure performed on a starting material used in the manufacture of the active substance. Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Change of name of manufacturer of the active		1:
Change of end of shelf-life specification for thiomersal content. Deletion of extraneous agents test on the finished product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/narmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. O2 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance. 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Change of name of manufacturer of the active	16 November 2023	
content. Deletion of extraneous agents test on the finished product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Change in test procedure performed on a starting material used in the manufacture of the active substance. 16 July 2012 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		
product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. 02 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure performed on a starting material used in the manufacture of the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance. Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Renewal Change of name of manufacturer of the active		
Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. Change in the manufacturing process of the active substance. 02 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance. Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Renewal Change of name of manufacturer of the active		Deletion of extraneous agents test on the finished
manufacturing practice in all countries. 19 August 2020 Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Change in test procedure performed on a starting material used in the manufacture of the active substance. Changes to an existing pharmacovigilance system as described in the DDPS O2 September 2011 Renewal O3 March 2011 Renewal Change of name of manufacturer of the active		product, based on assessment conducted in accordance Ph. Eur. 5.2.5.
Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. 02 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance. 19 December 2011 Change so an existing pharmacovigilance system as described in the DDPS 02 September 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		Update/harmonisation of the Part 2 dossier within current
holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. 11 January 2017 Change in the manufacturing process of the active substance. O2 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance. 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS O2 September 2011 Renewal O March 2011 Renewal Change of name of manufacturer of the active		manufacturing practice in all countries.
substance. O2 October 2014 Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. Change in test procedure performed on a starting material used in the manufacture of the active substance. Changes to an existing pharmacovigilance system as described in the DDPS O2 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal Change of name of manufacturer of the active	19 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive,
product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance. 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active	11 January 2017	j .
Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Deletion of a manufacturer for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Renewal 10 March 2011 Change of name of manufacturer of the active	02 October 2014	Change in a minor test procedure for this finished
Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		product.
substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance used in the manufacture of the active substance. 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		
Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance of the active substance. 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		
product. Replacement of a manufacturing site for the finished product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		
product. 12 December 2014 Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 10 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		·
Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. Change in test procedure performed on a starting material used in the manufacture of the active substance changes to an existing pharmacovigilance system as described in the DDPS Changes to an existing pharmacovigilance system as described in the DDPS Addition of a site for secondary packaging and batch release March 2011 Renewal Change of name of manufacturer of the active		
Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product. Change in test procedure for the active substance. Change in test procedure performed on a starting material used in the manufacture of the active substance Changes to an existing pharmacovigilance system as described in the DDPS Caseptember 2011 Addition of a site for secondary packaging and batch release March 2011 Renewal Change of name of manufacturer of the active	12 December 2014	
product. Deletion of a manufacturer of the finished product. 22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 10 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		
22 November 2013 Change in test procedure for the active substance. 16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		
16 July 2012 Change in test procedure performed on a starting material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		Deletion of a manufacturer of the finished product.
material used in the manufacture of the active substance 19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active	22 November 2013	Change in test procedure for the active substance.
19 December 2011 Changes to an existing pharmacovigilance system as described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active	16 July 2012	Change in test procedure performed on a starting
described in the DDPS 02 September 2011 Addition of a site for secondary packaging and batch release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active		material used in the manufacture of the active substance
release 29 March 2011 Renewal 10 March 2011 Change of name of manufacturer of the active	19 December 2011	described in the DDPS
10 March 2011 Change of name of manufacturer of the active	02 September 2011	
-	29 March 2011	Renewal
substance, plending, filling and assembly, quality control	10 March 2011	Change of name of manufacturer of the active substance, blending, filling and assembly, quality control

	testing, labelling and batch release
16 June 2010	Change of MAH
15 December 2009	Change of method of manufacture of the active substance
27 June 2008	Harmonisation of SPC
28 May 2008	Change of legal category from NFA-VPS to POM-VPS
16 November 2006	Change of legal category from P to NFA-VPS Changes to the SPC and Product Literature to bring in line with new legislation